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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 08/13/2009

Michael L. Goldman Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051 EXAMINER
CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1649 DATE MAILED: 08/13/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,919	03/26/2004	Thomas Wisniewski	57953/1211	9386
TITLE OF INVENTION: TREATMENT OF ALZHEIMER AMYLOID DEPOSITION (2003-11-WIS02)				

 APPLA, TYPE
 SMALL ENTITY
 ISSUE FEE DUE
 PUBLICATION FEE DUE
 PREV. PAID ISSUE FEE
 TOTAL FEE(S) DUE
 DATE DUE

 nonprovisional
 YES
 \$7.55
 \$300
 \$0
 \$10.55
 11/13/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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INSTRUCTIONS: This appropriate. All further indicated unless correcte maintenance fee notifical	ed below or directed oth	or trang the erwise	nsmitting the ISSU Patent, advance or in Block 1, by (a	i) specifying a new corre	spondence address;	and/o	r (b) indicating a sepa	ould be completed where correspondence address as rate "FEE ADDRESS" for
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Michael L. Gol Nixon Peabody I Clinton Square		/2009		I be	Cer	tificat	e of Mailing or Transi	
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Rochester, 141 1	4005-1051							(Signature)
								(Date)
APPLICATION NO.	FILING DATE			FIRST NAMED INVENTOR		ATTC	RNEY DOCKET NO.	CONFIRMATION NO.
10/810,919 TITLE OF INVENTION	03/26/2004 TREATMENT OF AL	ZHEIN	MER AMYLOID D	Thomas Wisnicwski EPOSITION		(2	57953/1211 2003-11-WIS02	9386
APPLN, TYPE	SMALL ENTITY	IS	SUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	PEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	10	\$755	\$300	\$0	J. L. L.	\$1055	11/13/2009
EXAM			ART UNIT	CLASS-SUBCLASS	1		\$1055	11110/2009
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Address form PTO/SE	ondence address (or Cha 3/122) attached. ication (or "Fee Address 2 or more recent) attach	-	-	or agents OR, alternati (2) the name of a single registered attorney or a registered patent attorney on the listed, no name will be	vely, ie firm (having as a agent) and the nam rneys or agents. If	memb	vera 2	
	ess an assignee is ident h in 37 CFR 3.11. Comp			THE PATENT (print or ty data will appear on the p T a substitute for filing an (B) RESIDENCE: (CITY	atent. If an assign assignment.			scument has been filed for
Please check the appropri	iate assignee category or	catego	ories (will not be pr	inted on the patent):	Individual 🚨 Co	orporat	ion or other private gro	up entity Government
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5. Change in Entity Star	tus (from status indicated s SMALL ENTITY statu			☐ b. Applicant is no lon				
NOTE: The Issue Fee and interest as shown by the	d Publication Fee (if req records of the United Sta	ired) tes Pat	will not be accepted ent and Trademark	from anyone other than t Office.	he applicant; a regi	stered	attorney or agent; or th	e assignee or other party in
Authorized Signature					Date			
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uns form and/or suggestions for reducing this barden, should be sent to the Cinet information Officer, O.S. Fatern and Trademark Office, O.S. Department of Commerce, P.O. Box 1450, Hazandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



Rochester, NY 14603-1051

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75	90 08/13/2009		EXAM	UNER
Michael L. Goldman			CHERNYSH	EV, OLGA N
Nixon Peabody LLP			ART UNIT	PAPER NUMBER
Clinton Square P.O. Box 31051			1649 DATE MAII ED: 08/13/200	9

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)		
10/810,919	WISNIEWSKI ET AL.		
Examiner	Art Unit		
Olga N. Chernyshey	1649		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative

herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to April 30, 2009. The allowed claim(s) is/are 1,8,9,12,19 and 20. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date

(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the

attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08).
- Paper No./Mail Date 1/30/08 ☐ Examiner's Comment Regarding Requirement for Deposit
- of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8. T Examiner's Statement of Reasons for Allowance

9. ☐ Other

/Olga N. Chernyshev/ Primary Examiner, Art Unit 1649 Application/Control Number: 10/810,919 Page 2

Art Unit: 1649

EXAMINER'S AMENDMENT

 An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tate L. Tishner on June 01, 2009.

The application has been amended as follows:

Claim 1. (Currently amended) A method of treating Alzheimer's Disease in a subject comprising:

administering to the subject an agent, wherein the agent

(1) is a protein comprising the an amino acid sequence of at least 5 of the amino acids, in sequence, of SEQ ID NO: 43, the protein including residue 18 residue 7 of SEQ ID NO:3 and having an amino acid substitution of the valine at residue 18 residue 7 which renders the protein

(2) is non-fibrillogenic, and

(2) (3) inhibits interaction between amyloid-β peptide and apolipoprotein E, compared to when the agent is absent, to treat Alzheimer's Disease in the subject.

 $\label{eq:claim 12.} \mbox{Claim 12. (Currently amended) A method of inhibiting accumulation of amyloid-β peptide deposits in a subject's brain comprising:$

administering to the subject an agent, wherein the agent

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Art Unit: 1649

(1) is a protein comprising the an amino acid sequence of at least 5 of the amino acids, in

sequence, of SEQ ID NO: 4 3, the protein including residue 18 residue 7 of SEQ ID

NO:3 and having an amino acid substitution of the valine at residue 18 residue 7 which

renders the protein

(2) is non-fibrillogenic, and

(2) (3) inhibits interaction between amyloid- β peptide and apolipoprotein E, compared to

when the agent is absent, to inhibit accumulation of amyloid- $\!\beta$ peptide deposits in the subject's

brain.

Cancel claims 5 and 27.

Claims 1, 8, 9, 12, 19 and 20 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

June 2, 2009

/Olga N. Chernyshev/ Primary Examiner, Art Unit 1649